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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/757,619	01/14/2004	Joseph John Michalowicz	OSTEONICS 3.0-480	4800
530	7590	11/29/2005	EXAMINER	
LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			AMARELD JR, ROBERT W	
			ART UNIT	PAPER NUMBER
			3738	

DATE MAILED: 11/29/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/757,619

Applicant(s)

MICHALOWICZ, JOSEPH JOHN

Examiner

Robert W. Amareld, Jr.

Art Unit

3738

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 January 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-52 is/are pending in the application.
- 4a) Of the above claim(s) 13-22 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-12 and 23-52 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 1/14/04.
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C.

121:

- I. Claims 1-12, 23-52 are drawn to a variable angle cutting block, classified in class 606, subclass 88.
- II. Claims 13-22 are drawn to a method of resecting bone, classified in class 606, subclass 88.

The inventions are distinct, each from the other because of the following reasons:

Inventions II and I are related as process and apparatus for its practice.

The inventions are distinct if it can be shown that either: (1) the process as claimed can be practiced by another materially different apparatus or **by hand**, or (2) the apparatus as claimed can be used to practice another and materially different process. (MPEP § 806.05(e)). In this case the process does not recite the necessary structure or means for positioning (claim 1c) the resection guide. The positioning could take place by hand without the structure of the arm (22), (claim 4) and recess, therefore the process could be carried out with another materially different apparatus than that of the claimed invention.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Art Unit: 3738

During a telephone conversation with Kevin Kocun on 11/17/05 a provisional election was made without traverse to prosecute the invention of Group I- a variable angle cutting block, claims 1-12, 23-52. Affirmation of this election must be made by applicant in replying to this Office action. Claims 13-12 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1, 3, 11, 23, 28, 35, 37, 51 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. These claims reference being "adjacent a bone" or "connected to said bone". The human body and bones are non-statutory subject matter and cannot be claimed with the structure of the invention. It is suggested that the applicant change the wording of the claims such that the device is "adapted to" be adjacent or connected to bone. The claims are replete with similar references to boney structure and should be thoroughly reviewed as to correct all such instances of recitation of the structure of the invention with non-statutory subject matter, namely bone. The claims will be examined as if these changes have already been implemented.

Art Unit: 3738

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-6, 8-12, 23-31, 33-45, 47-52 rejected under 35 U.S.C. 102(b) as being anticipated by Volk (US Pat# 4608898). Volk discloses a first portion (29) able to be fixed with respect to a bone surface, a second portion (20) rotatably coupled to the first portion at a pivot point (30) with a guide having guide surfaces (22, 23) and a means for positioning the first and second portions relative each other being an arm (27) with a hole receiving a bolt (pin) (36) and, being separate from the pivot point, the rotation of portion 1 relative to portion 2 maintains function if portion 1 is attached to bone. The first portion has tabs (38) with pins (screws) going through holes as shown in Figure 1 as a means for connection or fixing to bone and a recess between the washers of nut (33) and bolt (32), which are through a notch (34), in said recess, the arm is received where the bolt (32) is a screw mounted on the 1st and 2nd portions via washers and nuts (33) through the notch (34), the notch also being an aperture in the first portion. Guideway (20) (2nd portion) has a slot, with planar surfaces, for receiving a cutting tool (saw 53) and can be used for the tibia or the angular movement allows for varying to any angle including varus/valgus angles. A manual angle adjustment element is within the notch (34) as nuts (33) and a screw (32) and is near the angle pointer

Art Unit: 3738

(31) and is apart from the pivot point and may be loosened to allow for angle adjustment or tightened to lock portion 1 and 2 in relative position to each other. In reference to claim 37, the guide surfaces (23) may be regarded as the first and second ends of the second portion, where the pivot point of portion 1 and 2 is located on the first end of each portion and the angle adjustment engagement portion is located at the second end of the 1st portion. The axis of the resection surface being parallel with the pivot axis.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 7, 32, 46 are rejected under 35 U.S.C. 103(a) as being unpatentable over Volk (US Pat# 4608898) in view of Duffner (US Pat# 6796986) in further view of Goldin (US Pat# 4020929). Volk is explained supra, however Volk lacks a screw with a dimple to lock the arm in place. Duffner teaches a screw (175) to hold/lock pivoting arms of a guide in place (column 3, lines 35-45). Goldin teaches a screw with a dimple that slides into holes to lock a member in place (Figure 5 & 6). Goldin and Duffner also show that using a pin lock system is not a novel feature in the art. It would have been obvious to one of ordinary skill in the art at the time of the inventions to use the screw, as taught by Duffner

Art Unit: 3738

& Goldin with the guide of Volk such that it provides the ability to lock the arm in place.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. Egger, PGPub# US 20050070909-Saw jig for medical purposes ; Calton, PGPub# US 20050049603 –knee balancing block ;Rayhack, US Pat# 6007535 A- bone distraction; Burke, US Pat# 5484446 A- alignment guide; Ferrante, US Pat# 5275603 A- cutting guide; Pohl US Pat# 4703751 A- resecting guide & Konieczka, US 2823709 A- protractor for saw.

Please note the intended use, as set forth in the claims, carries no weight in the absence of any distinguishing structure. The replete references of use with bone, adjacent to bone, etc. do not introduce novel matter in that intended use in itself is not statutory.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert W. Amareld, Jr. whose telephone number is 571-272-6170. The examiner can normally be reached on M-F 9am - 5pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Corrine M. McDermott can be reached on 571-272-4754. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Art Unit: 3738

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Robert W Amareld, Jr.
Examiner
Art Unit 3738



RWA

BRIAN E. PELLEGRINO
PRIMARY EXAMINER

